

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/7/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claim 1, the examiner was unable to find support in the originally-filed disclosure for an outer covering tube that spans from a handle to a distal end; or an inner core surrounded by the outer covering from the handle to a distal end. Although Figures 2 and 3 show a handle, a distal end, and a cross-section at one location, there is no indication in this figure that the tube and core configuration span the entire length of the stylet.

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4. Similarly in regards to claims 7, 8, 10, 22, and 23, the examiner was unable to find support in the originally-filed disclosure that the claimed features span the length of the handle to the distal end.

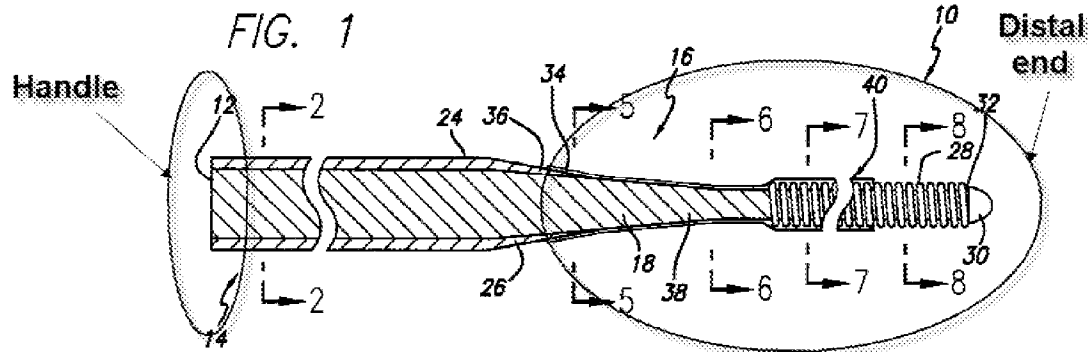
Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5-11, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrera (US 6,165,140, hereinafter "Ferrera").



7. In regards to claim 1, Ferrera discloses a stylet having a proximal end and distal end comprising a handle disposed on the proximal end (please see figure above - the noted region is a "handle" because it is capable of being gripped and the "distal end" can be considered an arbitrary distal portion of the stylet); an outer covering that is a tube spanning from the handle to the distal end (24) made of metal (col. 3, lines 20-25) and having a solid annular lateral cross-section (Fig. 2); and a solid inner core (12)

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surrounded by the outer covering from the handle to the distal end (see figure above) made of inner core material (col. 3, lines 1-5), wherein the outer and inner materials have different elastic and buckling properties (by virtue of the outer material being stainless steel and the inner material being Nitinol).

8. In regards to claim 5, the stylet is isodiametric between the handle and distal end (see figure above - the border of the "distal end" being considered the point where the outer sheath begins to taper).

9. In regards to claim 6, the inner core has a variable diameter along the length of the stylet (in the "distal end" - see figure above).

10. In regards to claim 7, the outer covering (24) has a substantially constant wall thickness from the handle to the distal end (see figure above - in this interpretation, "distal end" includes the tapered portion 26).

11. In regards to claim 8, the stylet has variable outer circumference along the length of the stylet from the handle to the distal end (see figure above - in this interpretation, "distal end" does not include tapered portion 26).

12. In regards to claim 9, the outer covering has a substantially constant wall thickness along the length of the stylet (between the "handle" and tapered portion 26).

13. In regards to claim 10, the inner core (12) has a substantially constant thickness along the length of the stylet from the handle to the distal end (see figure above).

14. In regards to claim 11, the inner core and outer material possess the claimed properties because they are materials disclosed by Applicant as possessing these properties (Nitinol and stainless steel, respectively).

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15. In regards to claim 22, the stylet comprises a distal and proximal end wherein the diameter of the inner core increases along the length of the stylet from the handle to the distal end of the stylet (see figure above - under this interpretation, the "distal end" and "handle" are on the opposite ends from those shown). Nothing in the claim language prohibits an arbitrary consideration of either end being "proximal" or "distal," such as a limitation drawn to the distal end being adapted for insertion into a lead, while the proximal end remains external to the lead. Further, there is no requirement that the "handle" cannot be capable of insertion into the lead, such as a requirement that the handle be of a larger diameter than the rest of the stylet.

16. In regards to claim 23, the stylet has a solid cross-section from the handle to the distal end of the stylet (Figs. 1 and 2).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 2-4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of Reynolds et al. (US 7,074,197, hereinafter “Reynolds”). Ferrera discloses the essential features of the claimed invention except for expressly disclosing that the inner core or outer covering is one of the claimed stainless steel alloys; an outer covering made of nitinol; or an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve. However, Reynolds teaches a means for attaching two different metals of a composite stylet structure (Fig. 2) comprising an outer sheath made of nitinol (26; col. 3, lines 51-60); an inner core or outer covering made of the claimed stainless steel alloys (24; col. 3, line 44); and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve (col. 4, lines 3-29) to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ferrera’s invention by providing a stylet having an outer sheath or inner core made of nitinol, an outer covering or inner core made of the claimed stainless steel alloys, and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy.

Response to Arguments

20. Applicant's arguments with respect to claims 1-13, 22, and 23 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762